

WHAT IS CLAIMED IS:

1. A composite device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising:
 - a first polymeric liner;
 - a second polymeric liner;
 - an intermediate structural member interposed between said first and said second polymeric liners, said intermediate structural member being defined by solid segments and openings therebetween such that the first liner can be bonded to the second liner through said openings to form at least one pocket about said solid segments; and
 - a bioactive agent located within said pocket about said solid segments of said intermediate structural member.
2. The device of claim 1, wherein said intermediate structure member is a stent having a generally cylindrical tubular body defined by said solid segments and said openings therebetween, said tubular body defining an inner surface and an opposed outer surface.
3. The device of claim 2, wherein said first and said second liners are adheringly joined at a location substantially coextensive with said inner surface of said tubular body.
4. The device of claim 2, wherein said solid stent segments include opposed inner and outer segment surfaces defining said inner and outer surfaces of said tubular body and opposed side segment surfaces between said inner and outer segment surfaces.
5. The device of claim 4, wherein said second liner is conformed to at least a portion of said side segment surfaces.
6. The device of claim 2, wherein said first polymeric liner is positioned about said inner surface of said tubular body.
7. The device of claim 2, wherein said second polymeric liner is positioned about said outer surface of said tubular body.

8. The device of claim 1, wherein said first liner defines a fluid contacting luminal surface.

9. The device of claim 1, wherein said bioactive agents in said reservoir are selected from the group consisting of antimicrobial agents, growth factors, anti-coagulant substances, stenosis inhibitors, thrombo-resistant agents, antibiotic agents, anti-tumor agents, anti-proliferative agents, growth hormones, antiviral agents, anti-angiogenic agents, angiogenic agents, anti-mitotic agents, anti-inflammatory agents, cell cycle regulating agents, genetic agents, cholesterol-lowering agents, vasodilating agents, agents that interfere with endogenous vasoactive mechanisms, hormones, their homologs, derivatives, fragments, pharmaceutical salts and combinations thereof.

10. The device of claim 1, wherein said solid segments of said intermediate structural member are foreign bodies, forming said pockets between said first and second liners thereabout.

11. The device of claim 1, wherein said bioactive agents in said reservoir are encapsulated in a polymeric matrix.

12. The device of claim 11, wherein said polymeric matrix containing said bioactive agent is a microparticle, microfiber or microfibril.

13. The device of claim 1, wherein said first liner and said second liner are independently selected from the group consisting of synthetic polymer, natural polymer or a combination thereof.

14. The device of claim 1, wherein at least one of said first or said second liners is porous.

15. The device of claim 13, wherein said synthetic polymer is selected from the group consisting of fluoropolymers, polyurethanes, polyurethane ethers, polyurethane esters, polyurethaneureas, polyimides, polyacrylamides, polyvinyl alcohols, polyphosphate esters, polyethersulfone, polyorthoesters, polyesters, siloxane polymers, silicones, polyvinylpyrrolidone,

polyvinyl ethers, polyethers, polycarbonate, polyalkylenes, polyamides, polyanhydrides, polyethylene oxides, polyvinyl aromatics, polyhydroxybutyrate valerate, polyhydroxybutyrate-co-hydroxyvalerate, polyacrylic acid and derivatives and mixtures thereof.

16. The device of claim 13, wherein said synthetic polymer is ePTFE.

17. The device of claim 13, wherein said natural polymer is selected from the group consisting of fibrin, elastin, celluloses, collagen, gelatin, vitronectin, fibronectin, laminin, reconstituted basement membrane matrices, starches, dextrans, alginates, hyaluronic acid, polylactic acid, polyglycolic acid, polypeptides, glycosaminoglycans, their derivatives synthetic analogs and mixtures thereof.

18. The device of claim 13, wherein said natural polymer and said synthetic polymer are biostable or bioabsorbable polymers.

19. The device of claim 2, wherein said stent is a biocompatible metal.

20. The device of claim 19, wherein said biocompatible metal is selected from the group consisting of stainless steel, platinum, gold, nitinol, tantalum and alloys thereof.

21. The device of claim 1, wherein said first and said second liners are of ePTFE.

22. The device of claim 14, wherein the porosity of said first liner is different from the porosity of said second liner.

23. The device of claim 21, wherein said first liner of ePTFE has pores of an internodal distance of greater than 40 microns and said second liner of ePTFE has pores of an internodal distance of less than 40 microns.

24. The device of claim 23, wherein said second liner exhibits a radial strength in excess of the radial strength of said first liner.

25. The device of claim 21, wherein said first liner of ePTFE has pores of an internodal distance of less than 40 microns and said second liner of ePTFE has pores of an internodal distance of greater than 40 microns

26. The device of claim 25, wherein said first liner exhibits a radial strength in excess of the radial strength of said second liner.

27. A composite intraluminal device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising:

- an elongate stent having a generally cylindrical tubular body defined by solid segments and openings between said solid segments, said tubular body defining an inner surface and an opposed outer surface;

- a first polymeric liner positioned about said inner surface of said tubular body;

- a second polymeric liner positioned about said outer surface of said tubular body; said second polymeric liner being joined to said first liner through said stent openings to form at least one pocket about said solid segments; and

- a bioactive agent located within said pocket about said solid segments of said tubular body.

28. A method of making an implantable composite device for delivery of bioactive agents associated therewith to a site of implantation of said device, said method comprising:

- providing an implantable prosthetic stent having a generally cylindrical tubular body defined by solid segments and spaces therebetween, said tubular body defining an inner surface and an opposed outer surface;

- applying a first polymeric liner to said inner surface;

- applying a second polymeric liner to said outer surface;

- joining said first and said second polymeric liners through said spaces between said stent segments to form a reservoir pocket adjacent to said solid segments; and

- filling said reservoir pocket with a bioactive agent for delivery of said bioactive agent to the site of implantation of said device.

29. The method of claim 28, wherein said joining is at a location coextensive with said inner surface portion of said tubular body.
30. The method of claim 28, further comprising providing said first polymeric liner on an elongate mandrel.
31. The method of claim 30, further comprising disposing said tubular stent over said first polymeric liner.
32. The method of claim 31, further comprising disposing said second polymeric liner over said disposed tubular stent.
33. The method of claim 32, further comprising compressing said disposed second tubular polymer liner through said openings of said stent and into contact with said first tubular polymeric liner.
34. The method of claim 28, wherein said joining of said first and said second polymeric liners comprises adhering, laminating or bonding said second tubular polymeric liner to said first polymeric liner at a location substantially coextensive with said inner surface of said tubular body of said stent.
35. The method of claim 28, wherein said filling comprises applying a vacuum and pressure to said device after said pocket is formed to remove air from said pocket for replacement with said bioactive agent.
36. The method of claim 28, wherein said filling comprises first encapsulating said bioactive agent in a polymeric matrix and subsequently mixing said encapsulated bioactive agent with a fluid or gel for delivery thereof to said pocket.

37. The method of claim 28, wherein said filling comprises injecting said pocket with said bioactive agent.
38. The method of claim 28, wherein said filling comprises delivering said bioactive agent to said pocket by use of a mini-pump attached to said pocket.
39. The method of claim 28, wherein said filling is performed prior to implantation of said device.
40. The method of claim 28, wherein said filling is performed following implantation of said device.
41. A method of making an implantable composite device for delivery of bioactive agents associated therewith to a site of implantation of said device, said method comprising:
- providing a first polymeric liner;
 - providing a second polymeric liner;
 - interposing an intermediate structural member between said first and second polymeric liners, said intermediate structural member being defined by solid segments and openings therebetween;
 - joining said first and second polymeric liners through said openings between said solid segments to form reservoir pockets adjacent to said solid segments; and filling said reservoir pockets with a bioactive agent for delivery of said bioactive agent to the site of implantation of said device.
42. A method for treating a lumen in a body, said method comprising:
- inserting a generally cylindrical implantable composite device for delivery of bioactive agents incorporated therewith into said lumen, the device comprising a first polymeric liner; a second polymeric liner; an intermediate structural member interposed between said first and second liners, said intermediate structural member being defined by solid segments and openings therebetween such that the first liner can be bonded to the second liner through said openings to form at least one pocket about said solid segments; and a bioactive agent located within said

pocket; and

affixing said implantable composite device to said lumen such that it will stay where positioned.

43. The method of claim 42, wherein said implantable composite device is inserted and/or accessed percutaneously.

44. The method of claim 42, wherein said implantable composite device is inserted and/or accessed using open or minimally invasive surgery.

45. The method of claim 42, wherein said bioactive agents are loaded into said pockets prior to or at the time of implant.

46. The method of claim 42, wherein said bioactive agents are loaded into said pockets after implant.

47. A method for treating a lumen in a body, said method comprising:

inserting an implantable composite device for delivery of bioactive agents incorporated therewith into said lumen, the device comprising an elongate stent having a generally cylindrical tubular body defined by solid segments and openings between said solid segments, said tubular body defining an inner surface and an opposed outer surface; a first polymer liner positioned about said inner surface of said tubular body; a second polymer liner positioned about said outer surface of said tubular body; said second polymer liner being joined to said first polymer liner through said stent openings to form a pocket about said solid segments; and a bioactive agent located within said pocket about said solid segments of said tubular body; and

affixing said implantable composite device to said lumen such that it will stay where positioned.